

REMARKS/ARGUMENTS

Claims 1-16 were pending in the application. Claim 15 was previously withdrawn pursuant to the Office's restriction requirement. Claim 1 is amended herein. It is submitted that no new matter has been introduced by the amendment to claim 1, with support found throughout the specification as filed. Claims 3, 6-14, and 16 are cancelled herein. Applicants reserve the right to file divisional or continuing applications directed to the subject matter of any claim withdrawn, amended or canceled for any reason. By the amendments or claim cancellations, Applicants do not acquiesce to the propriety of the Office's rejections and do not disclaim any subject matter to which Applicants are entitled. Cf. *Warner Jenkinson Co. v. Hilton-Davis Chem. Co.*, 41 USPQ.2d 1865 (US 1997).

The Office noted that the Information Disclosure Statement filed on October 8, 2007 allegedly failed to comply with 37 CFR §1.98(a)(2). Office Action mailed August 1, 2008 ("OA"), page 2. A corrected Information Disclosure Statement was filed August 12, 2008. Applicants request consideration and entry of the corrected Information Disclosure Statement.

I. 35 U.S.C. § 112 Rejection

Claims 1, 3 and 11-14 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement. OA, page 2. The Office states that the specification is enabling for serum-based immunoassay using anti-PLA2G13 and other art-known techniques. OA, page 2. Applicants agree that this subject matter is enabled. The Office argues, however, that the specification but does not reasonably provide enablement for an assay using a receptor molecule as recited in claim 3 or HCC imaging using anti-PLA2G13 as recited in claim 13. OA, pages 2-3. Here, Applicants respectfully disagree.

Without acquiescing to this ground of rejection, Applicants have cancelled claims 3 and 11-14, which were drawn to methods using a receptor molecule and methods utilizing detection of at least one cell-associated HCC-related protein. Claim 1 is amended herein to recite that the non-cell-associated HCC-related protein comprises phospholipase A2 group XIII, also referred to in the specification as PLA2G13. Methods of detecting the presence of HCC by assaying for this protein using

immunoassay or other art-known techniques are fully enabled by the specification, as indicated by the Office. OA, page 2.

Accordingly, reconsideration and withdrawal of this ground of rejection are respectfully requested.

II. 35 U.S.C. § 102 Rejections

A. Claims 1, 2 and 4 - Fujiyama

Claims 1, 2 and 4 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Fujiyama et al., *Hepat-Gastroenterol.* 33:201-205, 1986 ("Fujiyama"). OA, page 5. According to the Office, Fujiyama teaches that "plasma PIVKA-11 in HCC patients is elevated." OA, page 5. Applicants respectfully disagree.

As pending, claims 1, 2 and 4 recite that the non-cell-associated protein comprises PLA2G13. Fujiyama fails to disclose this protein, and also fails to disclose a method of assaying to determine the level of PLA2G13 for detecting the presence of HCC. Therefore, Fujiyama does not anticipate claims 1, 2 and 4.

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the pending rejections of claims 1, 2 and 4 under 35 U.S.C. § 102(b) based on Fujiyama.

B. Claims 6, 9, 11, 12 and 14 - Trojan

Claims 6-9, 11, 12 and 14 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Trojan et al., *The American Journal of Gastroenterology* 94:3314-3319, 1999 ("Trojan"). OA, page 5. According to the Office, Trojan teaches detecting mutant and wild-type p53 protein, and HCC imaging using ¹⁸F-FDG uptake. OA, page 5. The Office concludes that "the glucose molecule used meet[s] the limitation of ligand in ... claim 11." OA, page 5. Applicants respectfully disagree. Nonetheless, claims 6-9, 11, 12 and 14 have been cancelled in the present reply, so that this ground of rejection is rendered moot.

C. Claims 1, 2, 11, 12, 14 and 16 - Fan

Claims 1, 2, 11, 12, 14 and 16 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Fan et al., *J. Cancer Res. Clin Oncol.* 118:371-376, 1992 ("Fan"). Applicants respectfully disagree.

As noted above, claims 11, 12, 14 and 16 have been cancelled herein. By the amendment to claim 1 herein, claims 1 and 2 recite that the non-cell-associated protein comprises PLA2G13. In contrast, Fan teaches a correlation of alpha-fetoprotein level and HCC, as well as radioimmunoimaging of HCC using a labeled ferritin antibody. These teachings fail to anticipate detecting HCC using assays directed to PLA2G13.

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejections of claims 1 and 2 under 35 U.S.C. § 102.

CONCLUSION

Applicants have properly and fully addressed each of the Office's grounds for rejection. Applicants submit that the present application is now in condition for allowance. If the Examiner has any questions or believes further discussion will aid examination and advance prosecution of the application, a telephone call to the undersigned is invited. If there are any additional fees due in connection with the filing of this amendment, please charge the fees to undersigned's Deposit Account No. 50-3207. If any extensions or fees are not accounted for, such extension is requested and the associated fee should be charged to our deposit account.

Respectfully Submitted,

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